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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,437	09/08/2003	Wen-Ghih Tsang	021164-000310US	4741

20350 7590 05/18/2007  
TOWNSEND AND TOWNSEND AND CREW, LLP  
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SAN FRANCISCO, CA 94111-3834

EXAMINER
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DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/658,437

Applicant(s)

TSANG ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 35-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's Request for Continued Examination, amendment, response and affidavit filed on March 5, 2007 have been received and entered into the case. The IDS filed on September 14, 2006 has also been received and entered into the case. Claims 1 – 55 are pending; claims 1 – 5 and 35 – 55 are withdrawn from consideration; claims 6 – 34 have been considered on the merits, insofar as they read on the elected invention. All arguments and the affidavit have been fully considered.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 6 – 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fung et al. (US 6326201) in view of Shipley et al. (1997).

Applicant claims a method for obtaining a culture of propagating pancreatic cells, comprising isolating pancreatic cells from a pancreas, contacting the cells with a CD56 binding reagent, selecting the cells that bind to CD56, and separating the cells that do not bind to the CD56, to obtaining a culture of propagating pancreatic cells. The binding reagent is labeled; the cells are selected by FAS or panning; the binding reagent is an antibody that binds to the CD56 protein; the pancreas is human; the cells are further differentiated into an aggregate of insulin producing cells wherein differentiation comprises culturing the cells on plates coated with collagen IV. The media comprises a differentiation factor selected from hepatocyte growth factor (HGF), keratinocyte growth factor or exendin-4, specifically hepatocyte growth factor.

Fung teaches a method for obtaining a culture of pancreatic cells (abstract) the method comprising obtaining pancreas cells, culturing the cells, isolating viable cells, culturing the cells and differentiating the cells (col.10-11). The cells are obtained from human pancreas (col.11), the cells are selected by FAS or panning (col.14,19-20), the cells are differentiated into aggregates of insulin producing cells (col.12), the cells are differentiated with HGF (col.15), and/or are cultured with collagen IV (col.17). Fung teaches the cells are isolated using labeled antibodies (col.19-20).

Fung does not teach the method wherein the labeled antibody is CD56. However, at the time of the claimed invention, it was known in the art that pancreatic cells express CD56. In support, Shipley teaches CD56 is expressed in pancreatic islets, and that the marker can be used

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to isolate pancreatic cells (abstract, p.87,88). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to utilize CD56 as the labeled binding reagent of Fung, since it was a known marker of pancreatic cells, as evidenced by Shipley. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Shipley to use CD56 as the labeled binding reagent of Fung with a reasonable expectation for successfully obtaining a culture of propagating pancreatic cells.

### ***Response to Arguments***

Applicant argues that a prima facie case has not been made, in that there is not a motivation to combine or modify the references; that there is not a reasonable expectation for success; and that the references do not teach all of the claimed limitations. Applicant further argues that the claimed cells are undifferentiated or dedifferentiated cells, not islets as required by Shipley and that the claimed cells do not express the same markers as islets and therefore can not be identified in the same manner. Applicant further provides a declaration reiterating these points in addition to stating that differentiated cells can not predict or determine an undifferentiated cell and that one in the art would not expect the methods of Shipley to work with undifferentiated cells.

However, these arguments fail to persuade because the instant claims do not require the cells be undifferentiated or dedifferentiated, but that they are merely capable of proliferation over time (see spec. 0019). Moreover, the arguments are not commensurate in scope with the claimed invention.

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Regarding applicant's assertions that there is not a reason to combine/modify or a reasonable expectation of success, it is noted that Fung teaches the limitations of the claims except for the fact that the cells can be identified with CD56. Shipley clearly teaches that pancreatic cells are identified via CD56, and that they express the marker. This provides the motivation to one in the art to use the marker to first identify the pancreatic cells that are isolated from the pancreas.

While applicant has provided evidence that some undifferentiated cell types do not express differentiated cell markers, it is noted that these are not pancreatic cells, but lymphocytes and other proteins, thus the evidence is not commensurate in scope with the claimed cells.

For these reasons the claims stand rejected.

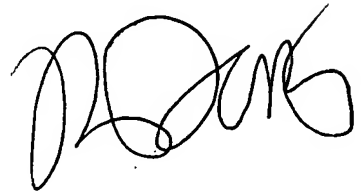
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis  
Primary Examiner  
Art Unit 1651

A handwritten signature in black ink, appearing to read 'Ruth A. Davis', is positioned to the right of the typed name and title.

May 10, 2007